



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

February 26, 2007

Docket No. 030-37392
Control No. 139970

License No. 37-23527-02

William Lynch
President
Isolite Corporation
31 Waterloo Avenue
Berwyn, PA 19312

SUBJECT: ISOLITE CORPORATION, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 139970

Dear Mr. Lynch:

This is in reference to your letter dated January 16, 2007 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Although your application states that you are requesting to possess and use licensed materials for sales displays and samples, it is our understanding based on various telephone conversations with you, that you also intend to be the initial importer in the United States, and therefore the U. S. "manufacturer" and initial distributor, for devices that are currently authorized for re-distribution pursuant to your License No. 37-23527-01G. If that is not correct, please inform us in writing.

An application for a manufacturer/distributor license for possession and use of radioactive material as the initial importer and manufacturer/distributor in the United States should be submitted in accordance with NUREG-1556, "Consolidated Guidance About Materials Licenses" (NUREG-1556), Volume 12, "Program Specific Guidance About Possession Licenses for Manufacturing and Distribution" (Vol. 12) instead of NUREG-1556, Volume 1 "Program Specific Guidance About Portable Gauge Licenses" (Vol. 1). Most of the following items will refer to the guidance in NUREG-1556, Vol. 12.

2. Items 3 and 5.1 of your application requests possession and use of luminous devices at trade shows and client sites as sales displays and samples. Note that these devices, which are authorized to be possessed and used pursuant to the general licenses of 10 CFR 31.5 or 10 CFR 31.7, are specifically-licensed devices when they are not used as described in the general licenses.
 - a. Confirm that you understand that all luminous devices authorized by this license must be possessed and used in accordance with the regulations of 10 CFR Parts 30 and 32 and the conditions of the license, and that they are NOT considered "generally-licensed devices" when possessed under the specific license.

- b. Provide the manufacturer's name and model number for each sealed source and/or device requested to be possessed pursuant to this license, including devices that are currently authorized for re-distribution pursuant to License No. 37-23527-01G, because possession and use of those devices will no longer be authorized under that license when the manufacturer/distributor license is issued.
 - c. Confirm that each sealed source and/or device is registered as an approved sealed source or device by the NRC or an Agreement State. At this time, you should provide the manufacturer and model numbers for the sources and/or devices currently authorized pursuant to your License No. 37-23527-01G. We cannot authorize devices that are undergoing review for a Sealed Source and Device Registration.
3. Item 5.1 of your application requests a possession limit of only 3,000 curies. Your current possession limit is 20,000 curies. Confirm that you currently possess 3,000 curies or less of tritium in all devices manufactured pursuant to 10 CFR 32.51 and 32.54 at your facility and possessed under this license. You should not include those signs that are installed at exit areas of your facility, in use pursuant to 10 CFR 31.5.
4. Item 5.1 of your application states that the proposed uses include 1) possession of products as sales displays and samples, and 2) redistribution of exempt products. However, your application dated January 16, 2007, to amend License No. 37-23527-01G states that you intend to possess a small quantity of products as sales inventory for urgent customer needs. Confirm that this additional activity should be authorized on this license, No. 37-23527-02, for possession of luminous devices.
5. Item 5.1 of your application requests re-distribution of exempt products such as gunsights. Such items are exempt from the requirements of a specific license once they have been initially distributed by a United States manufacturer pursuant to a valid license issued by the NRC for distribution of the exempt items. If you will be the initial importer and distributor in the United States, such items could be authorized by this possession license, however, a separate license for exempt distribution will be required. Confirm if you are, or are not, the initial importer and distributor in the United States. If so,
 - a. provide the manufacturer's name and model number for each sealed source and/or device requested;
 - b. confirm that each sealed source and/or device is registered as an approved sealed source or device by the NRC or an Agreement State;
 - c. confirm the maximum activity per source and/or device, and the requested maximum activity to be possessed at any one time under this license; and
 - d. submit an application for a license for distribution of exempt items pursuant 10 CFR 32.22 using the guidance found in NUREG-1556, Volume 8, "Program Specific Guidance About Exempt Distribution Licenses." Please note that the

application for an exempt distribution license would be submitted to the Rockville, Maryland office.

6. Item 5.2 of your application states that financial assurance and recordkeeping for decommissioning are not applicable, and that the threshold for providing financial assurance is 10 curies of unsealed tritium. This is not correct. Confirm that you understand that:
 - a. should you have breakage or other leakage of tritium from the specifically-licensed luminous sealed sources and/or devices that results in contamination of facilities, you may be required to amend your license to account for residual contamination from the unsealed tritium;
 - b. the requirements of 10 CFR 30.35 are applicable, and the possession of an amount of unsealed tritium in any quantity greater than 1 curie (not 10 curies) will require provision of financial assurance. (The applicable value for tritium from Appendix B to Part 30 is 1,000 microcuries or 1 millicurie. If you possess greater than 1 E3 times the applicable value [that is, greater than 1000 mCi or 1 curie] but less than or equal to 1 E4 times the applicable value, then you are required to provide financial assurance in the amount of \$225,000. If you possess greater than 1 E4 times the applicable value [that is, greater than 10 curies] but less than or equal to 1 E5 times the applicable value, then you are required to provide financial assurance in the amount of \$1,125,000. If you possess greater than 100 curies, then a Decommissioning Funding Plan is required and financial assurance in the amount of the cost estimate.); and
 - c. if sealed sources and/or devices break or otherwise leak, you will be required to maintain the record of such event as a record important for decommissioning, and will be required to demonstrate by surveys that your facilities meet the license termination criteria prior to release for unrestricted use. In addition, this requirement is applicable to temporary job sites.
7. Items 3 and 6 of your application request the use of the sealed sources and/or devices at temporary job sites (trade shows and client sites).
 - a. Confirm that you understand that the general licenses pursuant to 10 CFR 31.5 and 31.7 do not authorize the use of luminous devices at temporary job sites for sales and demonstrations.
 - b. Confirm that you understand that your NRC specific license can only authorize temporary job sites anywhere in the United States where NRC maintains jurisdiction, and that you must apply for reciprocity to possess and use the devices at temporary job sites in locations of Agreement State jurisdiction.
8. 10 CFR 32.55 describes quality assurance activities for luminous safety devices for use in aircraft, however, your application did not request authorization to perform such activities. State if you intend to perform such activities at your Berwyn location, and if so, describe the training, facilities, and radiation safety program for these activities. If

you do not intend to perform these activities at your Berwyn location, describe how you intend to meet these requirements.

9. We note that your application to amend License No. 37-23527-01G states you developed a quality management system with Shield Source Inc. that includes requirements for a quality assurance program that meets NRC requirements, and that Isolite's quality assurance program includes inspection of the Shield Source Inc. quality assurance program. Confirm if this quality management system addresses items pursuant to 10 CFR 32.51, 51a, and 52 as well as 10 CFR 32.53 through 32.56. Provide a description of the inspections such as the scope, frequency, and process for correcting any items identified. If this information was provided to the NRC as part of the Sealed Source and Device Registration Certificate application, you should state that, and you do not have to submit it again.
10. Item 6 of your application states that related companies, such as Self-Powered Lighting and Evenlite, may use the sample sources and/or devices at temporary job sites but that the possession and control of the licensed material would be performed officially by Isolite. Explain how Isolite will maintain possession and control of the licensed material if it is in use by persons from other companies at temporary job sites.
11. Item 7.1 of your application identifies you (William E. Lynch) as the safety officer, and states that you have sufficient experience to oversee the radiation safety program of a small company device-type license and distribution company. Because you are the initial importer of the devices, you are also responsible for ensuring that the imported devices meet the manufacturing requirements of 10 CFR 32.51, 51a, and 52 for the luminous devices and 10 CFR 32.53, 54, 55, and 56 for the aircraft signs, and that correct information regarding radiation safety and regulatory compliance is provided to customers. You are also responsible for the possession, use, transfer, shipping, and storage of devices by authorized persons under this license at your facilities in Berwyn and at temporary job sites under both normal use conditions and in incidents such as damage or breakage of devices. Considering the activities for which you would be responsible,
 - a. describe your formal training in the following areas:
 - i. principles and practices of radiation protection;
 - ii. radioactivity measurements standardization and monitoring techniques and instruments;
 - iii. mathematics and calculations basic to the use and measurement of radioactivity; and
 - iv. biological effects of radiation.
 - b. In addition, describe

- i. the specific radionuclides, forms, and quantities of each that you have handled, and
 - ii. where the experience was gained, the duration of the experience and the type of use(s) you performed.
12. Item 7.2 of the application provides general requirements for an assistant radiation safety officer, and Item 7.3 provides a general statement for training of salespersons who will be authorized users at temporary job sites. In accordance with NUREG-1556, Vol. 12, Section 8.7.2, provide the name of each person who will directly supervise the use of material, who will use material without supervision, or who will have responsibility for radiological safety, the types and quantities of materials they will use or supervise the use of, and information for each authorized user demonstrating that he or she is qualified by training and experience for these activities. Such information should include the type (on-the-job or formal course work), location, and duration of the training. Training should cover (a) principles and practices of radiation protection, (b) radioactivity measurements, standardization, and monitoring techniques and instruments, (c) mathematics and calculations basic to the use and measurement of radioactivity, and (d) biological effects of radiation. The description of the use of licensed materials should include the specific radionuclides handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use.
13. NUREG-1556, Vol. 12, Section 8.8, requires you to submit additional information about the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training. Item 8 of your application provides some of the required information, in part by the commitment that the training will meet the criteria listed in NUREG-1556, Vol. 1. In addition:
 - a. for shipping, sales, and other persons involved in providing information to customers of the generally-licensed devices, confirm that the topics covered will also include the conditions of the general licenses in 10 CFR 31.5 and 31.7.
 - b. confirm that anyone who prepares a package for shipment and/or transports radioactive material will be provided with training for hazmat employees as required by 49 CFR 172, Subpart H.
 - c. describe the minimum training that will be provided to persons providing oversight of the Part 32 requirements for the manufacture of the devices that will be authorized pursuant to this license. Describe the qualifications for the individual(s) that will provide such training.
 - d. in addition to routine refresher training at least every 3 years, confirm that training will be provided whenever there are significant changes in the applicable regulations, the conditions of your license, and/or your radiation safety program.

14. Item 9 of your application does not include a description or diagram of the areas assigned for the shipping and receiving of licensed materials. Provide this information. Diagrams should be drawn to a specified scale, or dimensions should be indicated.
15. Item 9 of your application does not address monitoring equipment used for monitoring of contamination of packages prior to shipment or for evaluation of potential contamination in the event of leakage or breakage of tritium sources. Item 10.3 of your application states that evaluation of wipes for contamination would be provided by an outside source, CoPhysics Corporation in New York. Confirm if you will use such outside sources to evaluate contamination on the exterior of packages prior to shipment to or from your Berwyn facilities and/or temporary job sites. If outside sources will be used to evaluate tests for contamination, confirm that you will verify that they are authorized by a valid license from the NRC or an Agreement State to perform the services you require. Also, confirm that material (samples) will be transferred in accordance with regulatory requirements. Alternately, provide a description of the equipment you will use to evaluate potential contamination.
16. In accordance with NUREG-1556, Vol. 12, Section 8.10.1, provide a description of your audit program for a) activities at your Berwyn facility, b) activities at temporary job sites, and c) activities that you will perform to ensure that imported devices sent directly to customers will meet the requirements for (1) luminous devices as specified in 10 CFR Parts 31.5 and 32.51, 32.51a, and 32.52 and (2) luminous devices in aircraft as specified in 10 CFR Parts 31.7 and 32.53, 32.54, 32.55, and 32.56.

The description(s) of your audit program(s) should address to the following topics:

- a. the objective(s) of the audit(s);
 - b. the scope of each audit;
 - c. the qualifications of individuals conducting the audits;
 - d. the techniques that will be used to perform audits;
 - e. the process you will use to address any problems and deficiencies identified during audits; and
 - f. the records that will be maintained of audits performed, the findings, and the corrective actions taken.
17. Item 10.4, "Material Receipt and Accountability" of your application states only that a physical inventory will be performed at intervals not to exceed 6 months. Section 8.10.3 of NUREG-1556, Vol. 12, discusses NRC's "material receipt and accountability" requirement to develop and implement procedures for activities such as ordering and receipt of licensed material, package opening, security of materials, transfer of materials, disposal of material, and recordkeeping and retention requirements. Confirm that you will develop and implement procedures such that your inventory and control system will have the capability to assure that licensed material possession limits are not

exceeded, that material possessed under the license in Berwyn or at temporary job sites is accountable at any given time, and records of receipt, transfer and disposal will be maintained as required by NRC regulation.

18. 10 CFR 20.1801 requires that licensed material be secured against unauthorized removal from the place of storage, and 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance over materials in unrestricted areas that are not in storage. In your application, you did not indicate how you will secure licensed material while at temporary job sites. Describe how you will preclude the unauthorized removal of licensed material from the place of storage and in unrestricted areas at temporary job sites, such as trade shows and client meetings.
19. Item 10.5 of your application states that the use of occupational dosimetry is not applicable to your program. However, monitoring for internal exposure could be required, in part, if an adult is likely to receive in 1 year an intake in excess of 10% of the annual limit of intake (ALI) for ingestion or inhalation. For tritium, the ALI is 80 millicuries for either ingestion or inhalation, therefore monitoring would be required if it were likely that an individual would receive an intake of greater than 8 millicuries of tritium. In accordance with NUREG-1556, Vol. 12, Section 8.10.4, determine if monitoring for internal exposure is required, and provide a response as indicated in that section.
20. Item 10.6 of your application does not address assessment of public dose from your licensed activities. In accordance with NUREG-1556, Vol. 12, Section 8.10.5, no response is required at this time. However, 10 CFR 20.1302 requires that you demonstrate compliance with the dose limits for individual members of the public, and 10 CFR 20.2107 requires that you maintain records sufficient to demonstrate such compliance. These issues will be reviewed during inspection. NUREG-1556, Vol. 12, Section 8.10.5 provides additional guidance for acceptable methods of demonstrating compliance with public dose limits.
21. Item 10.7 of your application commits to developing operating and emergency procedures to meet the criteria of NUREG-1556, Vol. 1, as applicable to tritium products. Some of this NUREG-1556, Vol. 1, criteria is applicable to the use of the tritium devices at temporary job sites, so long as the device is not damaged in any way. However, issues related to release of the tritium gas and tritium contamination should be addressed considering the guidance in NUREG-1556, Vol. 12. Confirm that your operating and emergency procedures will contain the following:
 - a. standard operating procedures for routine receipt, storage, control, inventory, security, and packaging for transportation of devices at your Berwyn facility;
 - b. standard operating procedures for receipt, storage, inventory, control, security and packaging for transportation of devices used at temporary job sites;
 - c. standard operating procedures for 10 CFR 32.55 quality assurance activities, if you intend to perform such activities at your Berwyn location;

- d. emergency procedures in the event of breakage or leakage of tritium that include instructions for contamination controls, personnel monitoring, contamination monitoring, use of protective clothing and equipment, recordkeeping requirements, reporting requirements, packaging and shipment of broken devices, and waste disposal requirements, which will be applicable at either the Berwyn facility or at temporary job sites;
 - e. procedures for customers, if you intend to provide instructions and/or materials to customers for return of intact devices to the manufacturer in Canada, or for transfer of broken devices from customers to an authorized facility.
22. In accordance with Section 8.10.6 of NUREG-1556, Vol. 12, provide a statement that “Procedures will be revised, only if: (1) the changes are reviewed and approved by the licensee management and the RSO in writing; (2) the licensee staff is provided training in the revised procedures prior to implementation; (3) the changes are in compliance with NRC regulations and the license; and (4) the changes do not degrade the effectiveness of the program.”
23. In accordance with Section 8.10.7 of NUREG-1556, Vol. 12, provide your procedures for routine surveys. We understand that you do not plan to work with unsealed materials, and that leak tests are not required for these devices. However, the use of the luminous devices at temporary job sites requires additional handling and multiple transfers which is not normally expected for such devices, and some routine surveys should be performed periodically throughout the year to ensure that devices are not damaged or leaking, and that facilities are not contaminated from devices that may be damaged and leaking.
24. Item 11 of your application does not provide waste management procedures for any tritium-contaminated waste generated as a result of a broken device. Confirm that any tritium-contaminated waste generated during retrieval and packaging of broken or damaged devices will also be sent to an authorized radioactive waste facility, or provide alternate procedures.
25. Based on a review of 10 CFR Part 110, you will require a specific license to export licensed materials in order to return luminous devices to Canada. The general license for export of byproduct materials states in 10 CFR 110.23(a)(1), “This section does not authorize the export of byproduct material to any embargoed country listed in 10 CFR 110.28, or byproduct material in radioactive waste, or tritium for recovery or recycle purposes.” You should review the regulations in 10 CFR Part 110, and contact the NRC’s Office of International Programs at (301) 415-2344 to help you with any additional questions you may have regarding import and export of luminous devices from Canada. An application for a specific license to export tritium for the purposes of recovery or recycling, or as radioactive waste, must be submitted directly to the Office of International Programs as described in 10 CFR Part 110, not to Region I.

Current NRC regulations and guidance are included on the NRC’s website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then

W. Lynch
Isolite Corporation

9

Toolkit Index Page. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 139970. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

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